REMARKS/ARGUMENTS

Claims 40-68 are active in this application. Support for the amendments to Claims 40, 48, 52, 56, and 60 is found in the specification on pages 17-19 and page 26, lines 7-15. Claim 54 is amended to change its dependency to Claim 52 thereby obviating the objection under 37 C.F.R. 1.75.

No new matter is believed to be added by the amendments submitted.

Applicant thanks the Examiner for the courtesy of discussing this case with the Applicant's undersigned representative on April 21, 2005. The following points were discussed during this meeting.

The undersigned noted that the rejection of Claims 63-68 under 35 U.S.C. § 112, first paragraph was untenable because the specification on page 15, line 9 clearly provides the adequate description needed for supporting these claims. Accordingly, withdrawal of this ground of rejection is requested.

The rejection of Claims 40, 44, 48, 50, 52, 56, 58, 60, and 62-68 under 35 U.S.C. § 112, first paragraph was also discussed during the above-noted meeting. With respect to those claims defining the phosphotransferase by sequence, the Examiner indicated that amending the claims relating homology to stringent hybridization conditions for the encoding polynucleotide, as has been allowed in the parent application (U.S. patent no. 6,642,038), would be favorably considered. The amendments submitted herein are believed to be consistent with the outcome of this discussion.

With respect to the enzyme claims defined by specific activity (Claims 63-68), the specification clearly enables one to make such enzymes. The specification on pages 14-15 describes, in detail, how to purify enzymes to this level of specific activity, noting that "specific activity" as commonly used in the field is an indicia of enzyme concentration in relation to contaminating material present from the crude extract from which the enzyme is

obtained. Furthermore, the application describes and enables the PT18 monoclonal antibody integral in the purification of the enzyme to this level of purity/specific activity, also noting that the antibody has been deposited. Still further, Applicant has described that the phosphotransferase enzyme is present in a number of divergent species, including human, rat, mouse, and drosophila. Accordingly, the invention claimed in Claims 63-68 is unquestionably enabled by the disclosure provided in the specification.

Withdrawal of the rejection pertaining to Claims 40, 44, 48, 50, 52, 56, 58, 60, and 62-68 under 35 U.S.C. § 112, first paragraph is requested.

Turning to the written description rejection of Claims 63-68, as noted above, the specification does describe a representative number of species providing the requisite written description for the claimed genus, i.e., the specification describes enzymes from human, rat, mouse, and drosophila. Accordingly, withdrawal of the rejection of Claims 63-68 under 35 U.S.C. § 112, first paragraph is requested.

During the above-noted discussion, the rejection of Claims 63-68 under 35 U.S.C. § 102(b) in view of Bao et al was also discussed. The undersigned noted that this publication does not enable the purification of the phosphotransferase enzyme because the antibody used for purification was not available to the public at that time. It was also noted that for a reference to be available for an anticipation rejection, the publication must enable the claimed invention. Further elaboration on this is provided below.

It is well-established law that in order for a reference to anticipate a claimed invention, the reference or references must provide an enabling disclosure sufficient to place the public in possession of the claimed invention.[1]

[1]See MPEP 2121.01 and *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968).

However, it was not until the filing of the present application where the specific antibody was disclosed and therefore enabled by deposition under the terms of the Budapest Treaty at the American Type Culture Collection as described on page 15, lines16 17 for the PT18 antibody (see the Preliminary Amendment filed on September 9, 2003) of the present specification, that such public availability was provided. Therefore, notwithstanding what Bao describes, the skilled artisan had no way to make the N-acetylglucosamine-1-phosphotransferase with the specific activities included in the present claims.

Thus, the core issue here is whether Bao et al enable the claimed enzymes.

Bao describes the purification of bovine N-acetylglucosamine-1-phosphotransferase (see Table II on page 31441) which was dependent on a specific monoclonal antibody—compare the specific activity of the enzyme in method I, Table I on page 31439 to the specific activity obtained when the purification used the antibody, Table II.

However, while Bao describes the identification of a hybridoma cell line producing the antibody required to purify the enzyme, the publication does not provide an enabling description for repeating the protocol to obtain the antibody and therefore, place that antibody into the public's possession. In fact, as described in Bao on page 31438, bottom of col. 2, the protocol used to identify the one antibody from a pool of millions of possible hybridoma cell lines required numerous steps and screenings. It is unlikely that one could successfully reproduce the protocol and, in fact, obtain the same antibody needed to purify the enzyme to such a high purity and specific activity. This is the very reason that the Patent Office imposes a deposit requirement for biological deposits on applications for patents (see 37 C.F.R. § 1.801-1.809 and MPEP, Chapter 2400): "When an invention relates to a new biological material, the material may not be reproducible even when detailed procedures and a complete taxonomic description are included in the specification." (*In re Lundak*, 227 USPQ 90, 93-94 (Fed. Cir. 1985)). See also MPEP § 2402 and *Ajinomoto Co. v Archer Daniels-Midland, Co.*,

56 USPQ2d 1332, 1337-1338: "The deposit of biological organisms for public availability satisfies the enablement requirement for materials that are not amenable to written description or that constitute unique biological materials which can not be duplicated."

Thus, using the Patent Office's own criteria, and applicable law for when biological deposit is required to enable an invention, it is clear that the Bao does not enable the purification of the N-actylglucosamine-1-phosphotransferase with a high specific activity, which is an element in the Claims 63-68.

Therefore, the present claims are not anticipated by the Bao publication and as such withdrawal of the rejection is requested.

Finally, the rejection of Claims 40-68 under the doctrine of obviousness double patenting in view of certain claims of U.S. 6,670,165 and 6,534,300[2] was discussed during the above-noted meeting. The undersigned pointed out that claims of these two patents relate to modified lysosomal hydrolases as well as methods of modifying the same but not claims directed to the phosphotransferase enzyme as claimed in the present application. While certain method claims in these patents use the phosphotransferase for modifying the lysosomal enzymes, the N-acetylglucosamine-1-phosphotransferase itself is not claimed in either of these two patents. Further, the text on page 2-5 of the specification discussing the relationship between lysosomal enzymes and the phosphotransferase enzyme was noted.

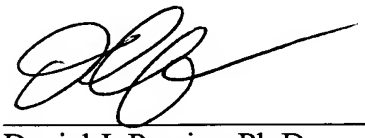
Accordingly and in view of the above, the rejection should be withdrawn.

[2] Note: the reference to U.S. patent no. 6,534,100 in the Office Action is clearly not relevant to the present application as it relates to Methods for treating cholesterol-containing foodstuffs using live ciliates.

Applicants request allowance of pending Claims 40-68.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Daniel J. Pereira, Ph.D.
Registration No. 45,518

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 06/04)